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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/864,930 | 05/24/2001 | Ronald Berenson | 980034.415 | 1690 |

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| EXAMINER |
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EWOLDT, GERALD R

| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 09/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,930

Applicant(s)

Berenson

Examiner

G.R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 5 6) ☐ Other:

DETAILED ACTION

1. Claims 1-5 are pending and being acted upon.

2. Claims 1-5 are objected to because of the following informalities:

The claims comprise incomplete sentences. Applicant is advised that the claims page should begin with "WE CLAIM" rather than "CLAIMS" such that when combined with the claims the combination comprises what can be considered a sentence, e.g., "we claim a method..." rather than "claims a method...".

Appropriate correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) the phrase "cell population", in Claim 1 should properly be "a cell population".

B) the phrase "selected from the group consisting of peripheral blood lymphocytes, T-cells, or activated T-cells", in Claim 1 comprises an improper Markush grouping. Members of a Markush grouping are properly equivalent type genuses, sub-genuses, or species. It is improper to form a Markush grouping wherein the each member of the grouping is a sub-member of the previous member, i.e., T cells are a sub-genus of peripheral blood lymphocytes and activated T cells are a sub-genus of T cells. These sorts of limitations are properly written as separate dependent claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by PR Newswire (07 December 1998).

PR Newswire teaches a method for the restoration or enhancement of immune function in immunocompromised or immunosuppressed patients (terminal non-Hodgkins lymphoma patients) comprising administering autologous T cells activated with anti-CD3 and anti-CD28 antibodies (see entire document).

The reference clearly anticipates the claimed invention.

7. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Henderson (21 December 1998).

Henderson teaches a method for the restoration or enhancement of immune function in immunocompromised or immunosuppressed patients (terminal non-Hodgkins lymphoma patients) comprising administering autologous T cells activated with anti-CD3 and anti-CD28 antibodies (see entire document).

The reference clearly anticipates the claimed invention.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for the restoration or enhancement of immune function in immunocompromised or immunosuppressed patients comprising administering **autologous** T cells activated with anti-CD3 and anti-CD28 antibodies,
does not reasonably provide enablement for:

a method for the restoration or enhancement of immune function in immunocompromised or immunosuppressed patients comprising administering **allogeneic** T cells activated with anti-CD3 and anti-CD28 antibodies.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of

predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

Regarding *in vivo* methods, said methods generally rely on unpredictable mechanisms, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling (MPEP 2164.03)." The MPEP further states that physiological activity can be considered inherently unpredictable. The state of the biological arts are such that the administration of activated allogeneic T cells to an immunocompromised or immunosuppressed patient would be considered to be highly unpredictable.

Graft Versus Host Diseases (GVHD) is a well-known condition wherein transplanted T cells attack host tissue. GVHD is often fatal. As set forth in U.S. Patent No. 6,447,765 (see particularly column 1, line 53 - column 2, line 15), before allogeneic bone marrow transplantation (a procedure which includes the transplantation of T cells) pre-transplant T cell depletion or inactivation is routine. Given the well-known dangers of allogeneic T cell transplantation, the intentional introduction of activated allogeneic T cells into an immunocompromised host would be considered to be highly unpredictable. While it is noted that under some conditions various states of immune tolerance have been achieved, the instant specification does not even address, much less enable, the establishment of immune tolerance. Accordingly, the herein established unpredictability of the claimed method would be considered to require undue experimentation.

It is noted that the specification discloses no examples (autologous nor allogeneic) of the claimed method. Thus, the prior art must be relied upon for the enabling of the claimed

invention. It is further noted that as recently as April 2003, the assignee has indicated in press releases that the claimed method is intended only for use with autologous T cells (see for example Bioventure View, 2003). As the prior art teaches the dangers and undesirability of transplanting activated allogeneic T cells, the invention of the instant claims must be considered to be highly unpredictable and requiring of undue experimentation.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of *in vivo* working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
September 09, 2003